

ORIGINAL PAPER

PÔVODNÁ PRÁCA

ADDITIONAL OUTCOME IMPROVEMENT IN THE REHABILITATION OF CHRONIC LOW BACK PAIN AFTER NUCLEAR RESONANCE THERAPY

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MOŽNOSŤ ZLEPŠENIA VÝSLEDKOV REHABILITÁCIE POMOCOU NUKLEÁRNEJ MAGNETICKEJ REZONANCIE PRI CHRONICKÝCH BOLESTIACH KRÍŽOV

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Summary

Additionally to a standardized physiotherapy programme, a treatment system basing on nuclear resonance (MBST[®] — Nuclear Resonance Therapy) was used in therapy of 62 rehabilitation patients suffering from chronic Low Back Pain. The study was performed double blind, placebo-controlled and randomised. Examinations were made at baseline, 1 week, and 3 months after application of a five-day Nuclear Resonance Therapy series. The intensity of pain was established by means of the Visual Analogue Scale (VAS), and restrictions by Low Back Pain were evaluated by means of the Oswestry Disability Questionnaire.

VAS measurements showed significant reduction of pain during rehabilitation in favour of MBST[®] after 3 months. The Oswestry total score improved significantly in both groups — standardized rehabilitation programme with and without nuclear resonance application — 1 week after therapy. 3 months after therapy, the Oswestry total score of the MBST[®] group remained significantly improved ($p < 0.01$) as compared with the placebo group. Major improvements were especially gained in the Oswestry section „personal care“. The condition of none of the patients with MBST[®] was worse after 3 months.

Hence, in future the MBST[®] — Nuclear Resonance Therapy may represent an additional treatment in rehabilitation of patients suffering from Low Back Pain. This additional treatment allows to further enhance the significant success in rehabilitation of spine related complaints.

Key words: MBST[®] — nuclear resonance therapy, low back pain, rehabilitation, Oswestry Disability Questionnaire.

Súhrn

Popri štandardizovanom fyzioterapeutickom programe sa pri liečbe 62 rehabilitovaných pacientov s chronickými bolesťami v oblasti lumbálnej chrbtice použil aj spôsob liečby založený na nukleárnej rezonancii (MBST Nuclear Resonance Therapy). Urobila sa dvojito zaslepená, placebo kontrolovaná a randomizovaná štúdia. Vyšetrenia sa robili na začiatku, 1 týždeň a 3 mesiace po aplikácii nukleárnej magnetickej rezonancie v 5-dňovej sérii. Intenzita bolestí sa určila pomocou vizuálnej analógovej škály (VAŠ) a zmeny bolestí v oblasti lumbálnej chrbtice sa vyhodnocovali pomocou dotazníka Oswestry Disability Questionnaire. Merania VAŠ ukázali významné zmiernenie bolesti počas rehabilitácie v prospech skupiny s MBST po troch mesiacoch. 1 týždeň po terapii sa celkový výsledok podľa dotazníka podstatne zlepšil v oboch skupinách — pri štandardizovanom rehabilitačnom programe s aplikáciou nukleárnej magnetickej rezonancie aj bez nej. Tri mesiace po terapii zostal celkový výsledok podstatne lepší ($p < 0,01$) v porovnaní s placebovou skupinou. Osobitne významné zlepšenie sa dosiahlo v položke „osobná starostlivosť“. U žiadneho pacienta s MBST nebol stav po 3 mesiacoch zhoršený. V budúcnosti môže nukleárna magnetická rezonancia ako dopĺňajúca liečba predstavovať prínos v rehabilitačnom programe u pacientov s bolesťami v oblasti lumbálnej chrbtice. MBST prispieva k rozšíreniu arzenálu prostriedkov fyzikálnej liečby a rehabilitácie.

KLúčové slová: MSBT — terapia nukleárnou magneticou rezonanciou, rehabilitácia pri bolestiach v oblasti lumbálnej chrbtice, Oswestry dotazník.

INTRODUCTION

Chronic Low Back Pain is the cause for a high number of labour related accidents and/or result in invalidity and therefore loss of the capacity to work. Therefore, directed pain reducing measures that remain effective over a longer period of time are not only beneficiary to the patient suffering from Low Back Pain, but also is of distinct socio-economic importance.

Novel rehabilitation concepts are now being tested in order to develop new interdisciplinary approaches to reducing pain-induced disabilities. In such multi-modal rehabilitation concepts for the treatment of patients suffering from chronic Low Back Pain, the active and passive physiotherapeutic measures are complemented by measures like Thermotherapy, Kryotherapy, Soft Laser Therapy, Electrotherapy and the application of magnetic fields in order to obtain relief of pain.

In the case of the therapy with static magnetic fields formed by means of permanent magnets, no results have been presented that have been obtained in a comparative study (comparisons before and after treatment, and comparison with a placebo group) and that survive scientific scrutiny (7). Treatment of chronic Low Back Pain with static magnetic fields formed by permanent magnets must therefore now be considered ineffective (2). The situation in the case of the use of pulsating magnetic fields, however, is quite different.

Pulsating electromagnetic fields (PEMF) have been successfully used in the treatment of bone fractures. The basis of this treatment is the knowledge that electromagnetic fields can stimulate cells as a reaction to changes in mechanical stress (11).

In the case of cartilage tissue and connective tissue structures, the electrical activities are somewhat more complex than in bone tissue, but the principle discussed above still remains valid. Changes of tension within collagen structures caused by differences in mechanical stress induce the transport of electrical signals to and from the tissue structures and thus have a positive effect on the metabolism (15). It has been shown that the pulsating electromagnetic fields (PEMF) procedure induces positive biological reactions such as cell proliferation, matrix construction, etc. (16). Because of the very different technical and physical basis, the results of the studies are hardly comparable.

A special form of nuclear magnetic resonance technique, a therapeutic procedure based on nuclear resonance, and known as MBST^R — Nuclear Resonance Therapy (10), has been developed recently. The active principle is based on the same principles as nuclear magnetic resonance diagnostic systems (MRI).

It has been established that Nuclear Resonance Therapy regenerates cartilage structures (9) and these results were

proven by nuclear resonance tomography. That study clearly showed an increase in both volume and thickness of cartilage in patients suffering from osteoarthritis of the knee. In a recently published randomised, double-blind study (3) chondrocytes and osteoblasts were treated in a nuclear resonance stimulator (MBS-Therapy). This treatment with nuclear resonance resulted in a very distinct augmentation of the growth rates of the cells as compared to those of the placebo group.

PEMF has been used in the treatment of chronic Low Back Pain and in the treatment of discogenic Low Back Pain as well as after spine fusions (12, 13). In contrast, as far as we know, the effect of MBST^R in the treatment of chronic Low Back Pain has hitherto not been studied.

It is by no means easy to render an objective evaluation of chronic Low Back Pain. This problem is mainly caused by the fact that „pain“ cannot be quantified. However, it is this objectively non-quantifiable symptom that controls patients' limitations and functional capacity, or in other words, their incapacity for, and reduction of, their everyday activities.

To document therapeutic results it is best to use specially developed and validated questionnaires for the evaluation of non-specific Low Back Pain (for example The Oswestry Low Back Pain Disability Questionnaire) (8). These questionnaires record all aspects involved, such as damage, activity, participation, and contextual matters. Such documented therapeutic results can form an important foundation for the evaluation of rehabilitative improvements in patients suffering from Low Back Pain.

PATIENTS AND METHODS

The study was designed as a placebo controlled, double blind, randomised multiple data study with a duration of three months. The study included 62 patients (36 males and 26 females, aged 18—71 years). Their mean age was 48.1 years. The intention to treat population of the study was a total of 62 patients. Data from 61 (per protocol population) of those patients could be evaluated. One patient was dismissed from the rehabilitation procedure for disciplinary reasons and removed from the study.

All patients suffered from Low Back Pain and had been admitted for a three-week in-patient rehabilitation therapy at the Specialised Hospital for Disorders of the Musculoskeletal System, Saalfelden part of the Pension Insurance Authority (PVA), Austria. The patients were diagnosed by the medical doctors using computer tomography or magnetic resonance procedures (MRI) as suffering from a verified disc prolapse. The following exclusion criteria were defined: Malignant diseases, bacterial infections, rheumatoid arthritis, HIV-positive patients, disorders of the cardio-vascular

system, arrhythmia, patients with a pacemaker, St.p. ICD-, insulin pumps, or total endoprosthesis of the hip, alcohol abuse, pregnancy and lactation.

Before the start of the study, all patient involved were given a detailed briefing about all aspects of the study as well as a printed information brochure about the therapy applied in the study. At the beginning of the study all patients signed a document stating that he/she agreed to be part of the study in accordance with the Helsinki Declaration (21).

In the context of a multi-disciplinary rehabilitation concept for spinal syndromes, all patients participated in a standardized, in-patient physiotherapy programme. This programme comprised gymnastics, mechanotherapy, massages, parafango applications, and medicinal baths. The therapeutic schedule excluded electrotherapeutic applications on the spine as well as hydroelectric baths.

All patients were subjected to a special therapy sequence on the damaged spinal regions. The therapy sequence consisted of five treatments of one hour each, on five consecutive days, in a magnetic nuclear resonance air-cored coil system (MBST — Nuclear Resonance Therapy). The total therapy duration with the MBS Therapy was thus five hours. The appliance used for the treatments was a nuclear resonance therapy system, version KSRT-Key K1B, type MBST 600 KSRT, serial number 12100015, produced and supplied by MedTec Medizintechnik GmbH, Wetzlar, Germany. The MBST[®] appliance constructs complex 3-dimensional therapy fields with the help of twelve independent, and independently controlled, coil systems that are, in part, spaced in an orthogonal pattern.

At the beginning of the treatment, the programme is loaded into the appliance using a computer chip card. Exact doses of MBS Therapy with a defined nuclear resonance field can thus be applied to the body areas that are to be treated. The patient rested comfortably on a couch, with the appropriate body part, the painful section of the spine positioned into the coil of the MBST appliance as described above.

The double-blind randomising was carried out by means of the coded chip cards. Thus, for half of the patients (Group I), the control unit activated the construction of the complex therapy fields (= Patients subjected to MBS Therapy = active MBST[®] Group; n = 30) whereas such therapy fields were not activated for the remaining patients (Group II), (= Patients not subjected to MBS Therapy = Nuclear Resonance Placebo Treatment; n = 32). The random selection was not known by patients, medical doctor or anyone involved in the therapeutic procedure.

An extensive clinical examination of each patient was carried out at the time of admittance to the rehabilitation clinic. Following that, important clinical factors were eval-

uated at the beginning of the MBST Study (Day 0), at one week after the termination of therapy, and at 3 months after the termination of therapy. The factors evaluated at those three points in time were: a) the peak level of pain, b) the mean level of pain on motion, and c) the level of pain at rest. For the evaluation the 10-part Visual Analogue Scale (VAS) was used.

For the evaluation of the disability caused by the chronic Low Back Pain, the Oswestry Low Back Pain Disability Questionnaire according to Fairbank et al (8) was used at the three evaluation times defined above. This validated clinical questionnaire for Low Back Pain was used in a modified version and comprises 52 single questions in 8 sections (Pain intensity, body care, lifting of heavy objects, walking, sitting, standing, sleeping, mobility for travel). The questionnaire is designed as a numeric evaluation.

The statistical evaluation was carried out with the help of SYSTAT version 9.0 Statistics for Windows (SPSS Inc., USA). The further statistical evaluation of the data from the Oswestry Score was done at the Institute for the Development of New Therapy Methods in Wetzlar, Germany, where the paired Wilcoxon Test and the paired Student-t Test were applied.

RESULTS

The pain level evaluations by means of the Visual Analogue Scale VAS (Tab. 1) showed clearly that the level of pain experienced by the patients of Group I as well as those of Group II was significantly reduced as early as one week after the start of the therapy procedure (Standard therapy programme + MBST[®] respectively placebo) and that this positive change for the patients suffering from chronic Low Back Pain was still recognizable 3 months after the end of the therapy in the statistical evaluation. One week after termination of the MBST[®] — Nuclear Resonance Therapy, however, an advantage for the patients belonging to the verum group (Group I) was clearly recognizable. The advantage was especially distinct in the section „Pain under Stress“ with a reduction from VAS 5.6 to VAS 3.3. This significant reduction for Group I could still be seen in the statistical results of the evaluation 3 months after termination of the therapy. In respect to the pain under stress, the MBST[®] group at the end of the three months period still showed a statistically significant reduction of pain of 23.2 %. For the placebo group, the reduction of pain at that time was no longer significant (13.8 %). Also the reduction of pain at rest seems to be still more significant after 3 months for the verum group with VAS 3.7—2.4—2.7 as compared to Group II for which the corresponding values are VAS 4.2—2.6—3.4. But this reduction of pain at rest, for both groups, 3 months after completion of the therapy was no longer signi-

Tab. 1. VISUAL ANALOGUE SCALE — Changes in pain level in rehabilitation patients suffering from Low Back Pain with (Group I) and without (Group II) additional MBST^R — Nuclear Resonance Therapy. * $p < 0.01$.

VAS (0-10)	Group I Rehabilitation + MBST ^R			Group II Rehabilitation + Placebo		
	Baseline	1 week	3 months	Baseline	1 week	3 months
Peak Pain level	7.9	5.1*	5.3*	8.1	5.8*	5.1*
Pain under stress	5.6	3.3*	4.3*	5.8	4.4*	5.0
Pain at rest	3.7	2.4*	2.7	4.2	2.6*	3.4

ficant as compared to the values at the beginning of the therapy. The values of the peak pain level during the study, in contrast showed no statistical difference between the two groups, indirectly indicating that the standardized stationary rehabilitation therapy is effective.

In the section „Pain Intensity,” the Oswestry Disability Questionnaire shows advantages for Group I with the Nuclear Resonance Verum Therapy. Indeed, 56.7 % already indicated a lower level of pain after 1 week. After 3 months, 48.2 % still indicated a lower level of pain (Fig. 1). After 3 months, Group I indicated a worsening of pain of 11.1 % whereas Group II at that time already had 31.0 % of pain worsening. However, in Group II there was still lowering of pain in 34.5 %, which as we have said before was less than the lowering of pain in the verum group (48.2 %) having been subjected to the nuclear resonance treatment (Fig. 1).

Parallel to the reduction of pain, functional loss caused by low back pain in Group I three months after completion of the therapy was reduced to 26.4 % as compared to the functional loss of 41.4 % at the beginning of the therapy (a reduction of 15 %). As Group II had, at the same point in time, a reduction of only 6.3 % (32.7 % as compared to 39.0 % at the beginning of the study), the advantage for the patients in Group I is obvious.

Of greater importance for the patient suffering of Low Back Pain seems to be the fact, that there was a great advantage for Group I in respect to the section „Personal Care.” In this respect 73.7 % in Group I indicated an improvement whereas 0.0 % experienced a worsening (!) (Fig. 2).

In the Oswestry Disability Questionnaire sections „Sitting,” „Standing,” and „Lifting” there also was an improvement during the entire study phase with light advantages for Group I. For the section „Walking,” the number of patients indicating an improvement was 10.0 % higher in Group I. After 3 months, however, the disadvantage for Group II had disappeared („Walking” better by 36.0 % for Group I as compared to an improvement of 41.4 % in Group II).

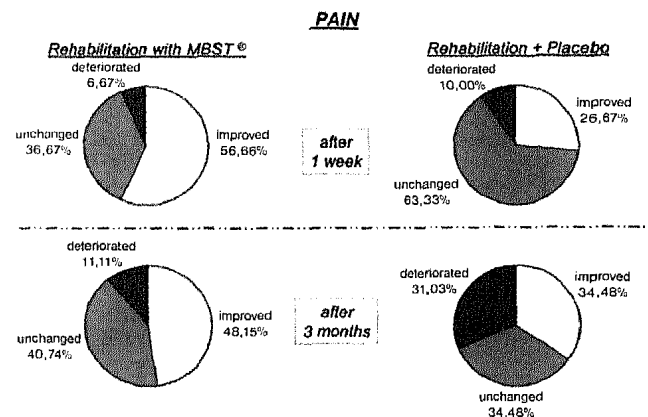


Fig. 1. Changes in the section PAIN of the OSWESTRY Disability Questionnaire in patients suffering from Low Back Pain with MBST^R — Nuclear Resonance Therapy or with placebo during in-patient rehabilitation.

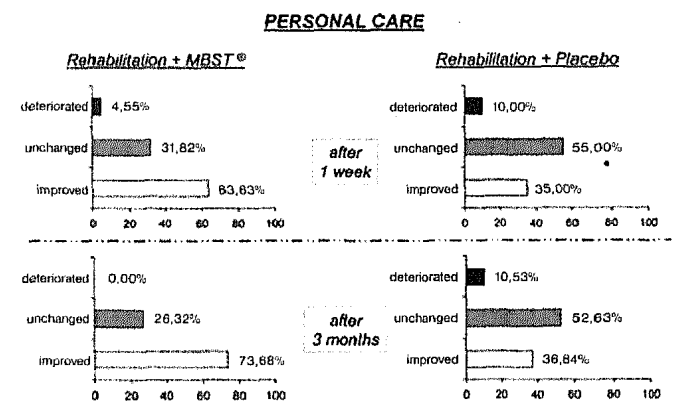


Fig. 2. Percentual changes in the section PERSONAL CARE of the OSWESTRY Disability Questionnaire in patients suffering from chronic Low Back Pain with or without MBST^R — Nuclear Resonance Therapy during in-patient standardized 3-week rehabilitation.

For the Group subjected to the MBS Therapy, there was 0.0 % worsening. In the placebo group, however, the worsening was with 20.7 % significant (Fig. 3). We could find no differences in section „Sleeping” as there still was an improvement in the sleeping conditions in both groups after three months (Group I: 75.0 %; Group II: 76.5 %).

As Group I showed a better result in respect to several sections of the Oswestry scores than Group II, it becomes evident that the total score at the measuring time of 1 week and three months after termination of the MBS Therapy shows a significantly greater improvement ($p < 0.001$) as compared to the results obtained in the placebo group (Fig. 4). After one week of placebo treatment there was a slight

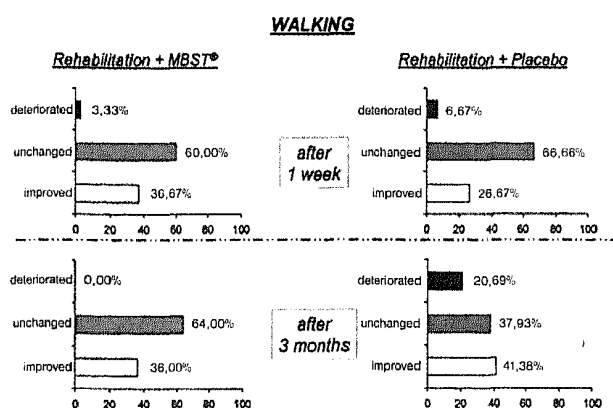


Fig. 3. Changes in the section WALKING of the OSWESTRY Disability Questionnaire in patients suffering from Low Back Pain with or without MBST[®]— Nuclear Resonance Therapy during in-patient rehabilitation.

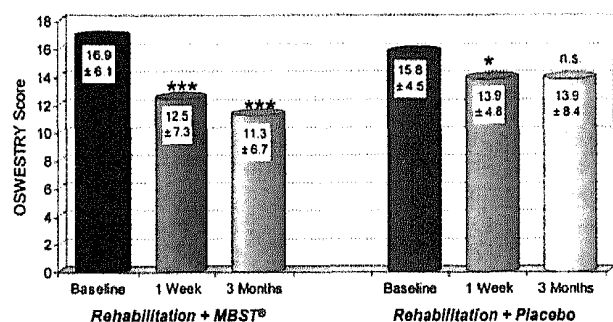


Fig. 4. OSWESTRY Disability Questionnaire — Changes in the TOTAL SCORE in patients suffering from Low Back Pain under the influence of an in-patient rehabilitation programme with/without MBST[®]— Nuclear Resonance Therapy. Significances 1 week and 3 months after therapy as compared against the values before the therapy: * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

($p < 0.05$) improvement in score of 15.80 to 13.87. The nearly unchanged mean values for Group II, however, proved to be no longer of any statistical importance because of the wider distribution after three months.

No negative effects arising from the MBST[®] could be recognised with any patients.

DISCUSSION

The prevalence of Low Back Pain, or in other words, the frequency of spinal pain during the whole life, is estimated to be 50 to 80 % (17, 19). This enormous prevalence of Low Back Pain causes considerable costs to the health care sys-

tem and is, therefore an important factor in the general socio-medical context of our life (18). Today, therapy results are generally evaluated in the context of back-specific function, pain, general health status, work capacity, and general satisfaction of the patients (5).

The Oswestry Questionnaire and the ten-part Visual Analogue Scale (VAS) for pain are useful for evaluating the results of Low Back Pain therapy for pain, incapacity and physical improvement (14).

The fact that classical physical therapy for chronic Low Back Pain (17) results in improvement at the symptomatic level (pain) and in everyday function in only about one third of rehabilitation patients clearly demonstrates the need for novel measures in this field.

MBST[®]— Nuclear Resonance Therapy is an interesting and effective approach to electro-therapy for regenerating cartilage or cartilage-like structures (9). According to Rothschild (15) the application of pulsating electromagnetic fields (PEMF) enhances DNA synthesis and collagen products. The special nuclear resonance field of MBST[®], however, can reactivate chondrocytes or may possibly even regenerate cells that have already been damaged. Indeed, this has already been shown in animal experiments (11) using the PEMF method. According to Valberg (20) the PEMF method can be used for the treatment of degenerated cartilage structures, but one must pay attention to the quality and quantity of the complex electromagnetic field. Although it is fact, that proper magnetic fields can stimulate cell growth (4, 6, 22), the PEMF results of the studies involved cannot be compared with the effects of nuclear resonance. In that context, the recently published proofs of enhancement of proliferation rates of chondrocytes and osteoblasts by means of MBST[®]— Nuclear Resonance Therapy (3) gain even greater importance.

The MBST[®] appliances generate a static magnetic field and a 3-dimensional radio frequency field, leading to the build-up of a nuclear resonance field at the site of the tissue that is to be treated. The nuclear resonance field has a pre-defined cell biorhythm frequency which is basically amplitude modulated with a modulation frequency similar to the nuclear resonance frequency. The purpose is to obtain the highest possible actively directed resonant energy transfer using the smallest possible field strength. This may well be the decisive therapeutic advance of MBST[®] as traditional magnetic field therapies are not capable of obtaining comparable results within an acceptable time limit.

The results of our study show that during a 3-week rehabilitation period with standardized physiotherapy, significant lowering of pain levels and an improvement in functionality as well as in personal care, walking, standing, and lifting can be obtained by adding MBST[®] to the treatment programme. In many sections of the Oswestry Scores, the patients treated with active MBST[®] had a significant advantage over the group of patients treated only with the standardized rehabilita-

tion programme and a MBST[®] placebo treatment. Especially the enhancements after three months observed in Group I show that the MBS Therapy can be responsible for the longer lasting rehabilitation results, especially in view of the fact that the placebo effects hardly bring a continuous enhancement over the period of three months. Improvements in respect to certain sections of the Oswestry scores within Group II (Patients with placebo treatment) can be explained by the fact that a standardized physiotherapeutic treatment within the stationary rehabilitation programme per se has a positive effect on Low Back Pain. This can especially be seen in respect to the sections „Walking“ and „Sleeping“ that show a comparable improvement for both groups at the end of the three months period after termination of the MBST[®].

As a general conclusion, we can state that we consider MBST[®] — Nuclear Resonance Therapy to be an additional, complementary, therapeutic method that is easy to apply. MBST[®] — Nuclear Resonance Therapy can very positively enhance therapeutic success in the rehabilitation of patients suffering from Low Back Pain, without side effects.

It would be interesting to show, in further studies, whether the positive impact of MBS Therapy remains after a period longer than the 12 weeks of our observation period. A structural modification of the cartilage tissue of the intervertebral joints or of the intervertebral discs remains, in our opinion an hypothesis requiring supporting scientific evidence. Such a structural improvement has hitherto only been shown for knee joint cartilage by a German research team (9).

Furthermore, it would be interesting to see whether the results of Aaron et al (1) can be confirmed by MBST[®]. This could show that electromagnetic fields could stimulate regulatory Cytokines such as the Transforming Growth Factor β that play a role in inflammatory processes.

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